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CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION FOUR

EXXON MOBIL CORPORATION, Plaintiff and Appellant, v. OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT et al., Defendants and Respondents.	B204987 (Los Angeles County Super. Ct. No. BS109343)

APPEAL from an order of the Superior Court of Los Angeles County, Michael C. Solner, Judge. Affirmed.

Latham & Watkins, William K. Rawson, Cassandra Sturkie, James L. Arnone, and Duncan Joseph Moore for Plaintiff and Appellant.

Edmund G. Brown, Jr., Attorney General, Ken Alex, Senior Assistant Attorney General, Edward G. Weil and Susan S. Fiering, Deputy Attorneys General, for Defendants and Respondents.

On April 20, 2007, respondent Office of Environmental Health Hazard Assessment (OEHHA)[1] listed di-isodecyl phthalate (DIDP) as a chemical known to cause reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health & Saf. Code, §§ 25249.5-25249.13), commonly known as Proposition 65. Appellant Exxon Mobil Corporation (Exxon) sought a writ of mandate challenging OEHHA's listing. The trial court denied the petition for writ of mandate, and Exxon appealed. Because we conclude that OEHHA did not abuse its discretion in listing DIDP as a chemical known to cause reproductive toxicity, we affirm.

STATUTORY BACKGROUND

I. Overview of Proposition 65

Californians adopted Proposition 65 through the voter initiative process in November 1986. The provisions of Proposition 65 were subsequently codified in Health and Safety Code sections 25249.5 through 25249.13.[2]

Proposition 65 requires that, at least once per year, the Governor shall cause to be published "a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter." (§ 25249.8, subd. (a).) The listing of a chemical triggers two requirements. The first requirement, contained in section 25249.5, prohibits businesses from discharging the chemical "into water or onto or into land where such chemical passes or probably will pass into any source of drinking water." The second, contained in section 25249.6, requires that businesses give "clear and reasonable warning" before exposing individuals to the chemical. (§ 25249.6 ["No person in the course of doing business shall knowingly and intentionally expose any individual to a

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[1] Joan E. Denton, the director of OEHHA, is also a respondent in this appeal.

[2] All further undesignated statutory references are to the Health and Safety Code.

chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . . ."].)

Even after a chemical has been listed, a discharge or release of the chemical is permitted under section 25249.9 if a business can demonstrate that the discharge or release "will not cause any significant amount of the discharged or released chemical to enter any source of drinking water." (Subd. (b)(1).) Similarly, under section 25249.10, a business need not warn of exposure to a listed chemical if it can demonstrate that the exposure "poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical . . . ." (§ 25249.10, subd. (c).)

Proposition 65 provides that the Governor "shall designate a lead agency" that "may adopt and modify regulations, standards, and permits as necessary to conform with and implement this chapter and to further its purposes." (§ 25249.12, subd. (a).) The Governor has designated OEHHA as the lead agency charged with implementing Proposition 65.[3] (Cal. Code Regs., tit. 27, § 25102, subd. (o); *Baxter Healthcare Corp. v. Denton*, *supra*, 120 Cal.App.4th 333, 346.)[4]

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[3] Prior to 1991, the lead agency was the Health and Welfare Agency. (*People ex rel. Lungren v. Superior Court* (1996) 14 Cal.4th 294, 309-310 & fn. 6; *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal.App.4th at p. 346, fn. 2.) For consistency and ease of reference, we will sometimes refer to the Health and Welfare Agency, while acting as the lead agency for Proposition 65, as OEHHA.

[4] While this case was pending, the Proposition 65 regulations were moved from title 22 to title 27 of the California Code of Regulations. All references to Regulations are to title 27 of the California Code of Regulations.

II. The Listing Process

A. The Statute—Section 25249.8

The focus of our inquiry in the present case is section 25249.8 ("the statute"), which governs the listing of chemicals under Proposition 65. As we have said, section 25249.8 requires that the Governor annually cause to be published "a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter." (§ 25249.8, subd. (a).) A chemical "is known to the state to cause cancer or reproductive toxicity" if

(1) "in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity," *or*

(2) "if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity," *or*

(3) "if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity." (§ 25249.8, subd. (b), italics added.)

Thus, the statute sets out three different ways by which a chemical can be listed. First, a chemical will be listed if the state's "qualified experts"—the Developmental and Reproductive Toxicant (DART) Identification Committee (for reproductive toxicants) or the Carcinogen Identification Committee (for carcinogens) (Regs., § 25102, subd. (c)(1)-(2))[5]—have determined that the chemical causes cancer or reproductive toxicity. Second, a chemical will be listed if "a body considered to be authoritative" has "formally identified" it as causing cancer or reproductive toxicity. Third, a chemical will be listed

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[5] The DART Identification Committee and the Carcinogen Identification Committee are Committees of the Science Advisory Board. (Regs., § 25302, subd. (a).) The predecessor to the Science Advisory Board (Board) was the Scientific Advisory Panel, whose members then acted as the "state's qualified experts." (*Baxter Healthcare Corp. v. Denton*, *supra*, 120 Cal.App.4th at p. 348; Final Statement of Reasons adopted in connection with regulation 25306(g), p. 1.) The DART Identification Committee and the Carcinogen Identification Committee are part of OEHHA. (Regs., § 25302, subd. (a).)

if a state or federal agency has required it to be labeled as causing cancer or reproductive toxicity. Our focus in the present case is on the second method, the so-called "authoritative body" provision of section 25249.8, subdivision (a).

B. The Regulations

Regulations promulgated by OEHHA and its predecessor, the Health and Welfare Agency, identify five agencies deemed "authoritative bodies" for purposes of identifying chemicals known to cause reproductive toxicity within the meaning of section 25249.8. A body is "considered to be authoritative" under this section if "the DART Identification Committee has identified [it] as having expertise in the identification of chemicals as causing reproductive toxicity." (Regs., § 25306, subd. (b).) The National Toxicology Program[6]—the authoritative body at issue in the present case—is one of the five identified agencies. The others are the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, the International Agency for Research on Cancer (solely as to transplacental carcinogenicity), and the National Institute for Occupational Safety and Health. (Regs., § 25306, subd. (*l*).)

The regulations provide that the "lead agency" (OEHHA) "shall determine which chemicals have been formally identified by an authoritative body as causing cancer or reproductive toxicity." (Regs., § 25306, subd. (c).) Further:

(1) A chemical is "*formally identified*" by an authoritative body when OEHHA determines that "the chemical has been included on a list of chemicals causing cancer or reproductive toxicity issued by the authoritative body; or is the subject of a report which is published by the authoritative body and which concludes that the chemical causes cancer or reproductive toxicity; or has otherwise been identified as causing cancer or reproductive toxicity by the authoritative body in a document that indicates that such

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6 The National Toxicology Program is designated an "authoritative body" "solely as to final reports of the National Toxicology Program's Center for Evaluation of Risks to Human Reproduction." (Regs., § 25306, subd. (*l*).)

identification is a final action." (Regs., § 25306, subd. (d).) Further, the list, report, or document must satisfy regulatory formalities. (*Ibid*.) It satisfies these formalities if it "specifically and accurately identifies the chemical" and has been (a) "[r]eviewed by an advisory committee in a public meeting, if a public meeting is required," or (b) "[m]ade subject to public review and comment prior to its issuance," or (c) "[p]ublished by the authoritative body in a publication, such as, but not limited to, the federal register for an authoritative body which is a federal agency," or (d) "[s]igned, where required, by the chief administrative officer of the authoritative body or a designee," or (e) "[a]dopted as a final rule by the authoritative body," or (f) "[o]therwise set forth in an official document utilized by the authoritative body for regulatory purposes." (Regs., § 25306, subd. (d)(2).)

(2) "*A*s *causing reproductive toxicity*" means either that "[s]tudies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity" (Regs., § 25306, subd. (g)(1)), *or*

> "Studies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible" (Regs., § 25306, subd. (g)(2)).[7]

The regulations further provide that OEHHA shall find that a chemical does not satisfy the definition of "causing reproductive toxicity" if "scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria of subsection (g), paragraph (1) or subsection (g), paragraph (2)."

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[7] "Reproductive toxicity" refers to adverse effects on the reproductive organs or reproductive performance of adult animals. "Developmental toxicity" refers to adverse effects on the developing fetus during gestation. Proposition 65 uses the term "reproductive toxicity" to refer to both.

(Regs., § 25306, subd. (h).) If objections are made to a listing decision, OEHHA shall refer the chemical to the DART Committee if it finds that "there is no substantial evidence that the criteria identified . . . in subsection (g) have been satisfied." (Regs., § 25306, subd. (i).)

FACTUAL AND PROCEDURAL BACKGROUND

I. Di-isodecyl Phthalate

Di-isodecyl phthalate, or DIDP, is a substance that is part of a group of chemicals known as phthalates. Phthalates are used primarily to soften and increase the flexibility of plastics. DIDP is used as a plasticizer in a wide variety of polyvinyl chloride (PVC) plastic products, including coverings on wires and cables, artificial leather, toys, carpet backing, and pool liners. It also has limited use in food packaging and handling. Approximately 135,000 metric tons (about 298 million pounds) of DIDP were used in the United States in 1998.

II. The Authoritative Body's Report

A. National Toxicology Program

The National Toxicology Program (NTP) is a federal interagency program that evaluates agents of public health concern. Three agencies form the core of NTP: the National Institute of Environmental Health Sciences of the National Institutes of Health, the National Institute for Occupational Safety and Health of the Centers of Disease Control and Prevention, and the National Center for Toxicology Research of the Food and Drug Administration. (http://ntp.niehs.nih.gov/?objectid=7201637B-BDB7-CEBA-F57E39896A08F1BB [as of Jan. 7, 2009]; http://ntp.niehs.nih.gov/?objectid=720163E9-BDB7-CEBA-FB0157221EB4375F [as of Jan. 7, 2009].)

In 1998, NTP and the National Institute of Environmental Health Sciences established the NTP Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) to evaluate the potentially hazardous effects of chemicals on human

reproduction and development. NTP-CERHR publishes monographs that assess the evidence that environmental chemicals cause adverse effects on reproduction and development and opine on whether these substances are hazardous for humans. (http://cerhr.niehs.nih.gov/about CERHR/index.html [as of Jan. 7, 2009].) NTP-CERHR monographs have three parts: (1) the NTP Brief on the chemical evaluated, (2) an Expert Panel Report, and (3) all public comments.

B. The Expert Report on DIDP

In 1999, NTP-CERHR initiated a review of seven phthalates, including DIDP. NTP-CERHR assembled an expert panel of scientists (expert panel) to review and evaluate the scientific evidence on the potential reproductive and developmental toxicities of each phthalate. Over 16 months, the expert panel critically reviewed more than 500 documents on the seven phthalates, held three public meetings, and received public comments.

The NTP-CERHR Expert Panel issued its report on DIDP, entitled "NTP-CERHR Expert Panel Report on Di-Isodecyl Phthalate" (the Expert Report), in October 2000. The report discussed five studies, four in rats and one in mice, that evaluated prenatal developmental toxicity following exposure to DIDP. In two of the studies, DIDP was administered to pregnant rats by "gavage," in which a small tube was inserted through the rat's mouth directly into the stomach. Both of these studies showed that fetuses exposed prenatally to DIDP had an increased incidence of skeletal abnormalities, including the growth of extra ribs. Two additional two-generation reproductive toxicity studies, in which female rats were exposed to DIDP through diet, also showed increased mortality rates and decreased birth weight among rat pups exposed prenatally to DIDP.

Based on these studies, the expert panel found that "[t]here are adequate data available in rats to determine that prenatal oral exposure to DIDP results in

developmental toxicity." Further, based on toxicokinetic[8] studies in rodents, the panel found that "[t]here is adequate general toxicokinetic data for DIDP, consisting of absorption, distribution, metabolism, and excretion, over a range of oral doses in the rat. . . . While studies of toxicokinetics in humans have not been located, the DIDP toxicokinetic data in rats are consistent with the large body of data on phthalates that include data on rodents and primates. It is reasonable to assume that the DIDP rodent data is relevant to humans."

The panel concluded: "The toxicology database is sufficient to determine that oral maternal exposure to DIDP can result in developmental toxicity to the conceptus. In rats, two prenatal developmental studies have shown effects on the developing skeletal system following oral exposure to DIDP. The NOAEL[9] for these studies was 40-100 mg/kg bw/day [milligram per kilogram of body weight per day]. In addition, developmental toxicity was noted in two oral two-generation reproductive toxicity studies in rats. Both studies showed effects on pup survival and growth. These effects may be due to prenatal and/or lactational exposures to DIDP. The NOAELs for the studies were 38-44 mg/kg bw/day during pregnancy and 52-114 mg/kg bw/day during lactation. Based on the results of the toxicology studies, oral exposure to pregnant humans and oral exposure to children should be examined."

C. The NTP Brief on DIDP

NTP issued a Monograph on the Potential Human Reproductive and Developmental Effects of Di-Isodecyl Phthalate in April 2003 (NTP Monograph). The

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[8] Toxicokinetics is "[t]he science that deals with the movement of harmful substances within the body (i.e., their absorption, distribution, metabolism, and excretion) and the relationship between the dose that enters the body and the amount of harmful substance found in the blood, urine, or other biologic specimens." (Am.Jur. Proof of Facts 3d, Attorney's Illustrated Medical Dict. (2002) p. T56.)

[9] "NOAEL" is the "no observable adverse effects level"—i.e., the level of exposure at which no adverse effects are observed. (*Fernandez v. California Dept. of Pesticide Regulation* (2008) 164 Cal.App.4th 1214, 1224.)

monograph included the Expert Report as well as NTP's Brief on Di-Isodecyl Phthalate (NTP Brief). The NTP Brief reached conclusions in four different areas about the developmental hazards posed by DIDP, as follows.

Are people exposed to DIDP? NTP concluded that people are exposed to DIDP during its manufacture, through the manufacture of DIDP-containing products, during the use of such products, or through the presence of DIDP in the environment. Environmental exposures can occur through air, water, or contact with DIDP-containing products. NTP noted, however, that studies to determine the extent of human exposures to DIDP have not been conducted. Therefore, based on exposures to di(2-ethylhexyl)phthalate (DEHP), a more widely-used phthalate, NTP estimated general population exposures to DIDP in the United States to be less than 3-30 µg/kg bw/day (micrograms per kilogram body weight per day).

Can DIDP affect human development or reproduction? NTP concluded that DIDP "possibly" affects human development or reproduction. It noted that while there is no direct evidence that exposure of people to DIDP adversely affects reproduction or development, studies with rats have shown that exposure to DIDP can cause adverse developmental effects. It thus concluded: "Scientific decisions concerning health risks are generally based on what is known as 'weight-of-the-evidence.' In this case, recognizing the lack of human data and the evidence of effects in laboratory animals, the NTP judges the scientific evidence sufficient to conclude that DIDP is a developmental toxicant and could adversely affect human development if the levels of exposure were sufficiently high."

Summary of supporting evidence. NTP noted that as presented in the expert panel report, DIDP studies in rats addressed effects on both development and reproduction. "These studies reported that exposure of pregnant dams to relatively high doses of DIDP causes abnormal development of the fetal skeleton, and reduced weight gain and survival of pups. In some instances, DIDP exposure was also associated with abnormalities of the urinary tract. The data also show that lactational exposure can contribute to reduced weight gain in pups."

Are current exposures to DIDP high enough to cause concern? NTP concluded that current exposures of people to DIDP are "probably not" high enough to cause concern. Although no data are available on general population exposures to DIDP, NTP judged it unlikely that human exposures are any greater than to DEHP, and thus it concluded that the scientific evidence does not point to an immediate concern for adverse reproductive or developmental effects. NTP thus concluded that, based on the assumption that the U.S. population is exposed to DIDP at less than 30 µg/kg bw/day, "there is minimal concern for developmental effects in fetuses and children." (Emphasis omitted.) However, NTP noted that "[i]nformation is not available on the levels of exposure in children mouthing DIDP-containing objects or in pregnant women occupationally exposed to DIDP. Thus, no conclusions can be reached concerning the possible hazards for these exposure circumstances."

III. OEHHA's Listing of DIDP

Based on the NTP Brief, in May 2004, OEHHA announced that it was investigating the possibility of listing DIDP as a chemical known to cause developmental toxicity pursuant to Proposition 65. In March 2005, OEHHA formally proposed to list DIDP as a chemical known to cause reproductive toxicity within the meaning of Proposition 65.

Exxon objected to the proposed listing, asserting that the NTP Brief did not consider the mandatory criteria under regulation 25306(g), and did not make the required determination that an association between adverse reproductive effects in humans and DIDP is biologically plausible. After a period of public comment, on April 20, 2007, OEHHA issued its final decision adding DIDP to the list of chemicals known to the state to cause reproductive toxicity.

IV. Mandate Proceeding

Exxon filed a petition for writ of mandate pursuant to Code of Civil Procedure section 1085 on June 8, 2007. OEHHA filed an answer July 18, 2007. The parties filed

briefs in support of and in opposition to the petition, and the trial court held a hearing on the matter on November 13, 2007.

The court denied the petition for writ of mandate on November 29, 2007, finding that "OEHHA did properly list DIPD [*sic*] as a developmental toxicant based on [an] appropriate finding by a designated authoritative body." Judgment was entered on December 19, 2007, and notice of entry of judgment was served on December 26, 2007.

Exxon filed a timely notice of appeal on January 10, 2008.

STANDARD OF REVIEW

Exxon filed a petition for a writ of ordinary (or "traditional") mandamus pursuant to Code of Civil Procedure section 1085.[10] "A traditional writ of mandate brought under Code of Civil Procedure section 1085 lies 'to compel the performance of an act which the law specifically enjoins, as a duty resulting from an office, trust, or station.' Under this section, mandate will lie to compel performance of a clear, present, and usually ministerial duty in cases where a petitioner has a clear, present and beneficial right to performance of that duty. [Citations.] Mandamus has long been recognized as the appropriate means by which to challenge a government official's refusal to implement a

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[10] An administrative agency's quasi-legislative actions generally must be challenged through traditional mandamus proceedings. (E.g., *Western States Petroleum Assn. v. Superior Court* (1995) 9 Cal.4th 559, 567.) In contrast, an action for administrative mandamus is appropriate "when the party seeks review of a 'determination, finding, or decision of a public agency, made as a result of a proceeding in which by law a hearing is required to be given, evidence is required to be taken and discretion in the determination of facts is vested in a public agency, on the grounds of noncompliance with [a statute],' generally referred to as an 'adjudicatory' or 'quasi-judicial' decision. [Citations.]" (*Id.* at pp. 566-567; see also *American Board of Cosmetic Surgery v. Medical Board of California* (2008) 162 Cal.App.4th 534, 547; *Bunnett v. Regents of University of California* (1995) 35 Cal.App.4th 843, 848 [distinguishing ordinary from administrative mandamus].) Because Exxon's petition seeks review of a quasi-legislative action by OEHHA—the listing of DIDP pursuant to Proposition 65—it is properly viewed as a petition for traditional mandamus.

duly enacted legislative measure. [Citation.]" (*Morris v. Harper* (2001) 94 Cal.App.4th 52, 58.)

In determining whether to grant a petition for traditional mandamus, we review for an abuse of discretion. "'"Abuse of discretion is established if the respondent [agency] has not proceeded in the manner required by law, the order or decision is not supported by the findings, or the findings are not supported by the evidence." [Citations.]' (*Sierra Club v. State Bd. of Forestry* (1994) 7 Cal.4th 1215, 1236.)" (*Environmental Protection & Information Center v. California Dept. of Forestry & Fire Protection* (2008) 44 Cal.4th 459, 478.) "In determining whether the agency complied with the required procedures and whether the agency's findings are supported by substantial evidence, the trial court and the appellate courts essentially perform identical roles. We review the record de novo and are not bound by the trial court's conclusions." (*Ibid*.)

A central issue in the present case is the meaning of the "authoritative body" provision of section 25249.8 and the regulations promulgated thereunder. As a general matter, courts "will be deferential to government agency interpretations of their own regulations, particularly when the interpretation involves matters within the agency's expertise and does not plainly conflict with a statutory mandate. (See *Yamaha Corp. of America v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 12-13.) . . . [W]e will not disturb the agency's determination without a demonstration that it is clearly unreasonable." (*Environmental Protection & Information Center v. California Dept. of Forestry & Fire Protection*, *supra*, 44 Cal.4th at p. 490.) While final responsibility for interpreting a statute or regulation rests with the courts and a court will not accept an agency interpretation that is clearly erroneous or unreasonable, "'[a]s a general rule, the courts defer to the agency charged with enforcing a regulation when interpreting a regulation because the agency possesses expertise in the subject area.'" (*Mileikowsky v. Tenet Healthsystem* (2005) 128 Cal.App.4th 531, 555.)

Also at issue in this case is whether OEHHA's listing of DIDP comports with section 25249.8 and the regulations promulgated thereunder. In considering this issue, the scope of our review "'is limited, out of deference to the agency's authority and

presumed expertise: "The court may not reweigh the evidence or substitute its judgment for that of the agency. [Citation.]"' [Citation.] 'In general . . . the inquiry is limited to whether the decision was arbitrary, capricious, or entirely lacking in evidentiary support . . . .' [Citation.] When making that inquiry, the '"'court must ensure that an agency has adequately considered all relevant factors, and has demonstrated a rational connection between those factors, the choice made, and the purposes of the enabling statute.' [Citation.]"' [Citation.]" (*American Board of Cosmetic Surgery v. Medical Board of California*, *supra*, 162 Cal.App.4th at pp. 547-548.) This limited judicial review is further constrained by the recognition that "'[i]n technical matters requiring the assistance of experts and the study of marshaled scientific data as reflected herein, courts will permit administrative agencies to work out their problems with as little judicial interference as possible.'" (*Western States Petroleum Assn. v. South Coast Air Quality Management Dist*. (2006) 136 Cal.App.4th 1012, 1018, quoting *Stauffer Chemical Co. v. Air Resources Board* (1982) 128 Cal.App.3d 789, 795.)

DISCUSSION

Exxon makes a series of arguments in support of its mandate petition.

First, Exxon contends that OEHHA may list a chemical based on the "authoritative body" provision of section 25249.8 *only* if an authoritative body's report includes the findings prescribed by regulation 25306(g)—i.e., that there are sufficient data from valid animal studies to demonstrate that adverse effects in humans are biologically plausible.

Second, Exxon contends that the NTP Brief, the authoritative body's report at issue in this case, did not include the findings required by regulation 25306(g). Thus, Exxon urges that OEHHA abused its discretion by listing DIDP pursuant to the statute's "authoritative body" provision.

Third, Exxon contends that OEHHA disregarded as "not relevant" factors that it legally must consider when making an authoritative body listing.

We discuss each of these contentions below.

I. An Authoritative Body's Report Need Not Make the Detailed Findings Set Out in Regulation 25306(g) to Support a Listing Decision

Exxon contends that for OEHHA to list a chemical using the authoritative body provision of section 25249.8, the authoritative body's report must meet the requirements of regulation 25306(c), (d), and (g). Where animal data are at issue, the report must "'take into account' the scientific criteria listed in (g)(2) (the analysis) and determine that effects in humans are biologically plausible (the conclusion)." In other words, Exxon contends, where the report relies on animal studies, it must conclude, among other things, that the "dose level" and "route of administration" in the animal studies are "'relevant to the expected human exposures.'" Further, the report must conclude that the developmental effects observed in experimental animals are "biologically plausible" in humans. According to Exxon, "An authoritative body report that neither 'takes into account' these scientific criteria nor contains the required finding of 'biological plausibility' in humans does not (and cannot) satisfy the requirements of [regulation 25306(g)(2)]. By definition, it cannot obviate the need for DART's review—which is the entire purpose of the authoritative body listing provision."

OEHHA disagrees. It contends that the authoritative body provision is triggered if a body considered authoritative under the statute identifies a chemical in a report, list, or other document as a developmental toxicant. The authoritative body's report must satisfy the "formality" requirements of the statute—that is, it must accurately identify the chemical, have been reviewed by an advisory committee in a public meeting, have been made subject to public review and comment, and have been adopted as a final report by the authoritative body—but it need not include the detailed findings set out in regulation 25306(g). Instead, once the chemical is "formally identified" by an authoritative body as a developmental toxicant, *OEHHA* reviews the scientific record before the authoritative body to determine whether there is substantial evidence to support a listing. If it concludes on the basis of its review that the regulation 25306(g) criteria are satisfied—

i.e., that the experimental animal data considered by the authoritative body are sufficient to support a conclusion that an association between adverse reproductive effects in humans and the toxic agent is biologically plausible—then it lists the chemical.

A. The Statute (Section 25249.8)

We begin our analysis with the language of the statute. (E.g., *In re J.L.* (2008) 168 Cal.App.4th 43, 55 [“‘To determine legislative intent, we turn first, to the words of the statute, giving them their usual and ordinary meaning’”]; *People v. Akhile* (2008) 167 Cal.App.4th 558, 563 [“We begin by examining the statutory language, giving the words their usual, ordinary meaning”].) As indicated above, the sole statutory source of the authoritative body provision is section 25249.8, which provides that a chemical is known to the state to cause cancer or reproductive toxicity within the meaning of Proposition 65 if

> “in the opinion of the state’s qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, *or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity*, or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.” (Subd. (b), italics added.)

The statute does not contain any additional language concerning the authoritative body provision. Thus, while the statute creates the authoritative body mechanism, it does not answer the question posed here about how the provision operates.

B. The Regulations

We turn next to the language of the regulations. As we have said, Proposition 65 expressly delegates to OEHHA the power to adopt regulations to implement its provisions. (§ 25249.12, subd. (a) [“The Governor shall designate a lead agency and other agencies that may be required to implement this chapter, including this section. Each agency so designated may adopt and modify regulations, standards, and permits as

necessary to conform with and implement this chapter and to further its purposes."].) Pursuant to this authority, OEHHA adopted regulation 25306, entitled "Chemicals Formally Identified by Authoritative Bodies."[11] Subdivision (c) of that section provides:

> "The lead agency shall determine which chemicals have been formally identified by an authoritative body as causing cancer or reproductive toxicity." (Regs., § 25306, subd. (c).)

Subdivision (g) further provides that, for purposes of this section, "as causing reproductive toxicity" means that

> "[s]tudies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." (Regs., § 25306, subd. (g)(2).)

Our analysis of the meaning of regulation 25306(c) and (g) necessarily is guided by the applicable standard of review. "As a starting point, the interpretation of an administrative regulation is subject to the same principles as the interpretation of a statute. [Citation.] However, there is an important difference between the interpretation of a statute and the interpretation of a regulation. '"The Legislature has no authority to interpret a statute."' [Citations.] On the other hand, where the language of the regulation is ambiguous, it is appropriate to consider the agency's interpretation. [Citation.] Indeed, we defer to an agency's interpretation of a regulation involving its area of expertise, '"unless the interpretation flies in the face of the clear language and purpose of the interpretive provision." [Citation.]' [Citation.]" (*County of Sacramento v. State Water Resources Control Bd*. (2007) 153 Cal.App.4th 1579, 1586-1587.)

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[11] Exxon has not claimed that the regulations at issue do not comply with the statute, and thus we assume for purposes of this opinion that they do.

Properly framed, thus, our inquiry is not the "correct" interpretation of regulation 25306(c) and (g), but whether the interpretation offered by OEHHA is reasonable in light of the regulation's language and purpose. For the reasons that follow, we conclude that it is.

As OEHHA notes, regulation 25306(c) expressly tasks it (the "lead agency") with determining which chemicals "have been formally identified by an authoritative body as causing . . . reproductive toxicity." Regulation 25306(g) further defines what it means to "caus[e] reproductive toxicity": "'as causing reproductive toxicity' means that . . . [s]tudies in experimental animals indicate that there are sufficient data . . . indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." To list a chemical pursuant to regulation 25306, therefore, OEHHA must conclude that an authoritative body has determined that the chemical is a reproductive toxicant—i.e., that the experimental animal data are sufficient to support a conclusion that adverse effects in humans are biologically plausible. Nothing in regulation 25306 suggests, however, that OEHHA must base this conclusion *solely* on the authoritative body's report. Rather, as OEHHA suggests, the language of regulation 25306 is broad enough to allow OEHHA to premise its conclusion on the authoritative body's report *and other factors*, such as the scientific literature on which the authoritative body relied and OEHHA's knowledge of the authoritative body's methodology. In other words, so long as OEHHA is able to conclude on the basis of the authoritative body's report *and the underlying scientific record* that an authoritative body has identified a chemical as a reproductive toxicant and that the identification takes the regulatory criteria into account, OEHHA may list it pursuant to regulation 25306.

Our interpretation of regulation 25306 is bolstered by subdivision (d)(1) of that section, which provides that the "formal identification" of a chemical may take the form of, among other things, a "list of chemicals." The regulatory history notes that lists were included in regulation 25306(d)(1) because "[l]ists and reports are methods of identification commonly used by governmental and non-governmental entities alike to identify chemical hazards." (Final Statement of Reasons adopted in connection with

regulation 25306(g), p. 9.) The fact that a list—"a series of names or other items written or printed together in a meaningful grouping or sequence so as to constitute a record" (Random House Webster's College Dict., p. 791 (1992))—is sufficient under this section suggests that an authoritative body's document need not detail the scientific criteria set forth in regulation 25306(g) to support a listing. Indeed, Exxon's notion that an authoritative body's document must discuss the regulation 25306(g) criteria is inconsistent with the regulation's clear statement that a "list" suffices.

Exxon asserts that OEHHA's interpretation of regulation 25306(g) "destroys the symmetry created by the statute, which establishes the same standard for DART and authoritative bodies." It explains that when the DART Committee lists a chemical, it is required to determine that "there is '[s]ufficient evidence . . . such that extrapolation to humans is appropriate.'" Further, it must consider the "'experimental design'" and "'overall protocol'" of the animal studies, and make an express finding "that '[t]he exposure [of the animals], in terms of route of administration, is relevant to expected human exposures.'" (Italics deleted.) Thus, Exxon suggests, to preserve the symmetry created by the statute, an authoritative body's report must contain the same findings that the DART Committee would make if it were undertaking a review of the chemical. Otherwise, it says, "the authoritative body['s] report has not obviated the need for DART's review."

We agree with Exxon that to support a listing, an authoritative body must have made the findings prescribed by the regulations. We further agree that the findings required by regulation 25306(g) in large measure parallel those made by the DART Committee when it reviews a chemical. We do not agree, however, that the authoritative body's *report* is the only permissible evidence that the authoritative body made the regulatory findings. Rather, as we have said, we believe that OEHHA properly can conclude that the authoritative body made the necessary findings based on OEHHA's review of the scientific literature on which the authoritative body relied and its knowledge of the authoritative body's methodology. So long as OEHHA can conclude, on the basis of the *entire record* before it, that the authoritative body made the regulation

25306(g) findings, it may list a chemical pursuant to the authoritative body provision of the statute.

C. The Final Statement of Reasons

Our conclusion that OEHHA's interpretation of regulation 25306 is a reasonable one is bolstered by the "Final Statement of Reasons" issued in connection with the regulatory adoption of regulation 25306. Government Code section 11346.9 requires agencies to prepare and submit with all adopted regulations a "final statement of reasons." (Subd. (a).) The "final statement of reasons" updates the "initial statement of reasons," which states "the specific purpose of each adoption . . . and the rationale for the determination by the agency that each adoption . . . is reasonably necessary to carry out the purpose for which it is proposed." (*Ibid.*; Gov. Code, § 11346.2, subd. (b)(1).) Both parties have relied on the Final Statement of Reasons adopted in connection with regulation 25306(g) (hereinafter, FSOR).

The FSOR notes that under the "primary approach" to listing, the Scientific Advisory Panel (the predecessor to the DART Committee) "must determine whether a chemical has been clearly shown, based upon scientifically valid testing according to generally accepted principles, to cause cancer or reproductive toxicity. This can be a time-consuming process." (FSOR, p. 6.) Thus, the apparent purpose of the "authoritative bodies" provision of Proposition 65 is "to establish a streamlined process for the Panel. Rather than review each chemical already subjected to review by another organization, the Panel needs only to determine the organization's competence. The chemicals which the organization has formally identified as causing cancer or reproductive toxicity can then be listed. This permits the Panel to focus its attention on chemicals which have not previously been evaluated." (FSOR, p. 6.)

The FSOR continues that under regulation 25306(g), a chemical may be identified as causing reproductive toxicity if, among other things, sufficient evidence of reproductive toxicity exists based on animal studies. "'Sufficient evidence' is defined to mean that there [are] sufficient data, which take into account the adequacy of the

experimental design and other specified parameters, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." (FSOR, p. 17.) However, "[i]t is not the intention of [OEHHA] to substitute its scientific judgment for that of the authoritative body. [OEHHA]'s inquiry will be limited to whether the authoritative body relied upon scientific data in an amount sufficient to conclude that the chemical causes reproductive toxicity. [OEHHA] does not intend by this section to go behind the studies relied upon by the authoritative body to determine their scientific validity. *Because the body is considered authoritative, and the body utilizes the same or substantially the same criteria as set forth in subsection (g), it will be assumed that the data relied upon is scientifically valid.* [OEHHA] will look to determine whether the authoritative body relied upon animal or human data in an amount sufficient to satisfy the criteria. If so, the chemical will be proposed for listing." (FSOR, pp. 17-18, italics added.)

Further, "[a]s indicated above, [OEHHA] does not intend to substitute its scientific judgment for that of the authoritative body. It does not intend to reevalu[a]te the science to determine whether the authoritative body should have reached a different result. *In effect, there is a presumption that the authoritative body properly applied the criteria*." (FSOR, p. 20, italics added.)

Considered together, we understand these statements to mean that when designating a body as authoritative within the meaning of the statute, the DART Committee determines whether the body uses "the same or substantially the same criteria" set out in regulation 25306(g). Only if it does will it be deemed an "authoritative body." The authoritative body designation thus allows OEHHA to *presume* that the body made the prescribed findings when it determined a chemical to be a reproductive toxicant: "In effect, there is a presumption that the authoritative body properly applied the criteria." (FSOR, p. 20.)

D. Western Crop Protection Assn. v. Davis

We conclude finally that our analysis is consistent with the Court of Appeal's in *Western Crop Protection Assn. v. Davis* (2000) 80 Cal.App.4th 741. There, OEHHA proposed to list several chemicals based on the Environmental Protection Agency's (EPA) designation of the chemicals as "known to cause" or "reasonably . . . anticipated to cause" reproductive toxicity. (*Id*. at pp. 745-748.) Appellants sought a writ of mandate to block the proposed listing, contending that the federal "reasonably . . . anticipated to cause" standard was lower than Proposition 65's "known to cause" standard. (*Id*. at p. 748.) OEHHA responded that the language used by the EPA in articulating its standard did not preclude it from finding that the EPA had made the requisite Proposition 65 identification. In other words, OEHHA said, regardless of the semantic formulation used by the EPA, it was authorized to examine the data on which the EPA acted to determine if its listing satisfied the state standard. (*Ibid*.)

The Court of Appeal adopted OEHHA's position and denied the writ. Assuming without deciding that the EPA standard was less rigorous than the Proposition 65 standard, it concluded that "it does not follow that it is improper for the state to find that a *particular* chemical has been placed on the [EPA] list, 'i.e., formally identified,' by the EPA 'as causing . . . reproductive toxicity.' It can do so by determining whether the reasons for the EPA placement meet the [Proposition 65] criteria." (*Western Crop Protection*, *supra*, 80 Cal.App.4th at pp. 751-752.) In other words, the court said, "[i]f it can be objectively ascertained that the reason the EPA placed a particular chemical on the . . . list is because it found sufficient evidence of reproductive toxicity to qualify under the California definition, that suffices to meet the criteria of the California law." (*Id*. at p. 752.)

Further, the court concluded, regulation 25306(i) implies that OEHHA has the authority to apply the regulation 25306(g) criteria to the administrative record on which the EPA relied to determine whether the chemical meets the California standard. "We conclude that under section 12306 [now, 25306], OEHHA has the authority to examine the administrative record of the [EPA] procedure to determine if there is substantial

evidence that the EPA has placed a chemical on the EPA list because it meets the state's criteria of 'causing . . . reproductive toxicity.' If so, . . . the fact that the federal standard may be broad enough to allow inclusion of chemicals on the [EPA list] that do not satisfy the California standard does not prevent OEHHA from determining that a chemical was placed on the [list] by EPA 'as . . . causing reproductive toxicity.'" (*Western Crop Protection, supra*, 80 Cal.App.4th at p. 754.)

The court's analysis in *Western Crop* is consistent with our analysis. As we have done here, the court in *Western Crop* found that an authoritative body's failure to discuss the Proposition 65 listing criteria in its report does not preclude OEHHA from finding that a chemical has been formally identified by an authoritative body as causing reproductive toxicity. Instead, OEHHA may consider the *entire record*, including both the authoritative body identification and the record on which it relied, to determine whether a chemical has been formally identified as causing reproductive toxicity.

II. The NTP Brief on DIDP and the Underlying Administrative Record Adequately Supported OEHHA's Listing Decision

Having resolved the central legal issue raised by this case—the circumstances under which OEHHA may determine that a chemical has been formally identified by an authoritative body as causing reproductive toxicity—we now turn to the facts. Specifically, we consider whether OEHHA abused its discretion by concluding that NTP formally identified DIDP as a reproductive toxicant, and further by finding that substantial evidence supported that identification. For the reasons that follow, we conclude that there was no abuse of discretion.

A. OEHHA Did Not Abuse Its Discretion by Concluding That NTP "Formally Identified" DIDP "As Causing . . . Reproductive Toxicity"

The parties do not dispute that the NTP Brief on DIDP is a final report that satisfies the procedural requirements of regulation 25306(d)(2). The sole area of

disagreement is whether the brief identified DIDP as a reproductive toxicant in the manner the statute and regulations require. We conclude that it does.

The NTP Brief unambiguously identified DIDP as a developmental toxicant. It stated: "Scientific decisions concerning health risks are generally based on what is known as 'weight-of-the-evidence.' In this case, recognizing the lack of human data and the evidence of effects in laboratory animals, *the NTP judges the scientific evidence sufficient to conclude that DIDP is a developmental toxicant and could adversely affect human development* if the levels of exposure were sufficiently high." (Italics added.) Based on this statement, there can be little doubt that NTP made the determination pivotal to the authoritative body scheme: That DIDP is a developmental toxicant in humans.

The question, therefore, is whether OEHHA reasonably concluded that NTP considered the factors prescribed by regulation 25306(g) (adequacy of the experimental data, sufficiency of the data, biological plausibility in humans) when it determined DIDP to be a developmental toxicant. As we have said, OEHHA was not limited to the NTP Brief in making this determination; under regulation 25306(g), it was entitled to consider the whole record before NTP, including the scientific literature on which NTP relied. In this case, however, it did not need to do so, because the Expert Report contained the analysis necessary for OEHHA to conclude that NTP adequately had considered the regulatory criteria.

Adequacy of the experimental design. The Expert Report reflects that the expert panel considered the adequacy of the experimental designs in concluding that DIDP is a developmental toxicant. Specifically, the Expert Report reflects that the panel considered the number of relevant studies, the route of administration employed in each study, the number of test animals, and the dosage levels. For example, with regard to one prenatal developmental toxicity study, the expert panel noted that the experimental animals (Sprague-Dawley rats) were dosed by gavage, the study used 25 animals per test group, and doses were 0, 100, 500, and 1,000 mg/kg bw/day. With regard to another study, it

noted that the experimental animals (Wistar rats) were also dosed by gavage, the study used 10 animals per test group, and doses were 0, 40, 200, and 1,000 mg/kg bw/day.

Sufficiency of the data. The Expert Report reflects that the expert panel also considered the sufficiency of the data in concluding that DIDP is a developmental toxicant. The Expert Report specifically finds that "*[t]here are adequate data available in rats to determine that prenatal oral exposure to DIDP results in developmental toxicity*." (Italics added.) Further, it explains the basis for this conclusion: "The results of [two rat studies] were remarkably consistent and included increases in lumbar and cervical ribs," an effect "seen infrequently in controls." Further, the appearance of extra ribs was "identical at the common dose of 1,000 mg/kg bw/day in the 2 studies" and "[i]n the study where there was a larger group size (n=25), the litter incidence at this dose [1,000 mg/kg bw/day] for each effect (cervical and lumbar) achieved statistical significance." Finally, the report noted that a "numeric trend of increased incidence with increased dose was seen at all doses."

Biological plausibility in humans. The Expert Report expressly noted that humans may be exposed to DIDP as a result of uptake by food animals, certain vegetables, and migration of DIDP from food packaging. Further, it said, while studies of toxicokinetics in humans had not been located, "the DIDP toxicokinetic data in rats are consistent with the large body of data on phthalates that includes data on rodents and primates." Thus, it concluded, "It is reasonable to assume that the DIDP rodent data [are] relevant to humans." Further, the Expert Report said: "There are no human data from which to assess the health effects associated with DIDP exposure; studies of DIDP toxicity are limited to laboratory animals. *In the absence of human data to the contrary, it is assumed that the effects observed in laboratory animals are relevant to humans.*" (Italics added.)

Exxon does not contest the existence of these findings, but it contends they are irrelevant because "NTP-CERHR, not the Expert Panel, is the designated authoritative body in this case." Thus, it contends, "[s]tatements in the [Expert Report] are . . . relevant only to the extent that NTP clearly adopted or relied on such statements." We do not agree. As indicated above, we have concluded that it was proper for OEHHA to

examine the *whole record*, including both the authoritative body identification and the record on which it relied, to determine whether NTP made the findings prescribed by regulation 25306(g). (See Discussion, part I.B, *ante*.) The Expert Report is part of the record on which NTP relied. OEHHA thus did not abuse its discretion in examining, among other things, the Expert Report.

Exxon also contends that the Expert Report is insufficient because it contains an inadequate discussion of routes of exposure. It says: "The Expert Panel Report, while referring to the routes of administration used in the rat studies, contains no discussion of whether those routes of administration, and the resulting high doses achieved, were relevant to potential human exposures to DIDP." We do not agree. As we have said, the expert panel expressly found that "[h]umans may be exposed to DIDP by . . . oral . . . routes of exposure" and "consumer exposure [to DIDP] occurs primarily by oral and dermal routes." Further, it found that "[d]irect exposure may . . . occur through food as a result of uptake by food animals, certain vegetables, and migration of DIDP from food packaging." Thus, the Expert Report contains express support for its conclusion that the rodent studies on which it relied, in which the animals were dosed orally (by gavage or in the feed), were "relevant to humans."

Exxon further contends: "The Expert Panel also did not discuss the relationship of the routes of administration to DIDP's physical properties for purposes of expected human exposure. Neither NTP nor the Expert Panel discussed or even acknowledged DIDP's high molecular weight or low vapor pressure, volatility, and water solubility in the context of potential human exposure. [Citation to record.] Nor did they address how these properties naturally limit the amount of DIDP that can enter the human body, or whether the oral routes of administration in the rat studies—and the high doses achieved—were relevant to potential human exposures to DIDP."

We do not agree that the Expert Report was required to discuss these factors. As OEHHA notes, while these factors are relevant to DIDP's *water* solubility, they are irrelevant to its *fat* solubility or its ability to contaminate food. (See Discussion, part II.B.2, *post*.) Since the rat studies cited in the Expert Report relied on dissolving

DIDP in oil or mixing it with the animals' feed, DIDP's low water solubility does not appear to be relevant to the expert panel's conclusions.

B. OEHHA Did Not Abuse Its Discretion by Finding Substantial Evidence That the Scientific Record Before NTP Satisfied the Proposition 65 Criteria

Exxon contends that OEHHA abused its discretion by concluding, on the basis of the scientific record before NTP, that there was substantial evidence that the criteria identified in regulation 25306(g) had been satisfied. (Regs., § 25306, subd. (i).) Specifically, Exxon urges that: (1) OEHHA applied an incorrect standard under which findings in experimental animals alone will trigger a listing; and (2) OEHHA disregarded as "not relevant" factors that must be considered for an authoritative body listing. For the reasons that follow, we disagree.

1. OEHHA Did Not Abuse Its Discretion by Basing Its Listing Decision on Experimental Animal Data

Exxon urges that OEHHA abused its discretion by basing its listing decision solely on data derived from experimental animal studies. According to Exxon, if regulation 25306(g)(2) could be satisfied based solely on animal findings, the "bar" would be "lower[ed]" for authoritative body listings: "Because [experimental animal studies] are *designed* to show adverse effects in laboratory animals [citation], the consequence of OEHHA's interpretation is that virtually any chemical tested in animals would 'trigger a listing' under [regulation 25306(g)(2)], even if the authoritative body never discussed the relevance of the animal findings to humans. . . . [I]t is not hard to see how this standard could lead to the very 'unrestrained listing' of chemicals that [regulation 25306(g)(2)] was designed to prevent."

We do not agree with Exxon that OEHHA's finding of substantial evidence based on an extrapolation to humans from experimental animal studies was an abuse of discretion. As noted above, regulation 25306 expressly permits a finding of reproductive toxicity to be based on experimental animal studies, so long as the studies indicate that

"there are sufficient data . . . indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible." (Regs., § 25306, subd. (g)(2).) Nothing in the regulation thus precludes OEHHA from concluding that there is substantial evidence of biological plausibility based solely on animal studies—to the contrary, the regulation appears to contemplate extrapolation from animal studies to humans.

Further, there is support in the record for OEHHA's assertion that it is a "generally accepted toxicological assumption that, absent evidence to the contrary, a chemical that causes developmental harm in experimental animals, will cause similar harm in humans." In this regard, the Guidelines for Developmental Toxicity Risk Assessment promulgated by the federal Environmental Protection Agency state: "[I]t is assumed that an agent that produces an adverse developmental effect in experimental animal studies will potentially pose a hazard to humans following sufficient exposure during development. This assumption is based on the comparisons of data for agents known to cause human developmental toxicity [citations], which indicate that, in almost all cases, experimental animal data are predictive of a developmental effect in humans."[12] NTP apparently operates under a similar assumption: "In the absence of human data to the contrary, it is assumed that the effects observed in laboratory animals are relevant to humans." (See also *AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, 438, fn. 7 ["The qualitative assessment of carcinogenic risks to humans ordinarily is based on data from experiments in animals. (Guidelines for Chemical Carcinogen Risk Assessments and their Scientific Rationale, Cal. Health and Welfare Agency, Dept. of Health Services (Nov. 1985) p. C-20 [hereafter cited as *California Cancer Guidelines*].) It is unethical to test humans, and because of the 20-to 30-year latency period of many human cancers, epidemiological studies do not adequately warn humans and protect them from the risk of exposure to

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[12] The EPA guidelines continue: "The most appropriate species is used to estimate human risk when data are available (e.g., pharmacokinetics). In the absence of such data, it is assumed that the most sensitive species is appropriate for use, based on observations that humans are as sensitive or more so than the most sensitive animal species tested for the majority of agents known to cause human developmental toxicity."

new carcinogens. (*Id*. at p. B-10.) For recognized human carcinogens, the first evidence of carcinogenicity frequently is found in test animals; only afterwards are cancer effects looked for, and found, in humans. (*Id*. at p. B-24.) Thus, the principle which supports qualitative animal to human extrapolation from carcinogenesis 'has been accepted by all health and regulatory agencies and is regarded widely by scientists in industry and academia as a justifiable and necessary inference.' (Rep., Office of Science and Technology Policy, 50 Fed.Reg. 10375 (Mar. 14, 1985).)"].)

Exxon urges that in *Baxter Healthcare Corp. v. Denton*, *supra*, 120 Cal.App.4th 333, a case involving DEHP and cancer risks, the Court of Appeal held that animal findings are not automatically relevant to humans. We do not agree that *Baxter Healthcare* can be read so broadly. There, Baxter Healthcare demonstrated that the mechanism that caused liver cancer in laboratory mice did not operate in humans exposed to DEHP. (*Id*. at p. 350.) For this reason, the Court of Appeal concluded that there was substantial evidence supporting the superior court's conclusion that DEHP did not pose a significant risk of cancer in humans. (*Id*. at p. 371.) *Baxter Healthcare* thus only stands for the proposition that *in some cases*—namely, those cases where experimental animals and humans differ from one another in physiologically significant ways—extrapolation to humans from animal studies is not appropriate. It does *not* stand for the proposition that extrapolation from animals to humans is inappropriate in the absence of such evidence. Because Exxon has not suggested that rat and human physiology differ in ways that make extrapolation from DIDP rat toxicity studies inappropriate, *Baxter Healthcare* is irrelevant to our analysis.

2. <u>OEHHA Did Not Abuse Its Discretion by Rejecting Exxon's Contention That DIDP Cannot Enter the Human Body in Biologically Significant Amounts</u>

Exxon contends finally that OEHHA abused its discretion by rejecting Exxon's contention that DIDP cannot enter the human body in biologically significant amounts. It explains that DIDP is characterized by low vapor pressure (a low maximum possible

concentration in air), low volatility (a slow evaporation rate), low solubility in water, and relatively high molecular weight (larger size molecular structure). Accordingly, it contends, the amount of DIDP that can enter the human body in the air as vapor or in water is scientifically insignificant—i.e., it is thousands or millions of times below the amount of DIDP found to have adverse effects in laboratory animals. In other words, Exxon suggests, "a person could breathe air with DIDP at its theoretical maximum concentration for a lifetime, or drink water containing DIDP at its solubility limit every day, and still have no health risk." Exxon also suggests that DIDP's physical properties preclude significant exposure in food or through the skin. Thus, Exxon contends, "because of DIDP's intrinsic properties, the routes of administration and dosages used in the two rat studies are not relevant, and cannot be extrapolated, to expected human exposures."

OEHHA's response is twofold. First, it rejects Exxon's contention that DIDP cannot enter the human body in biologically significant amounts. In this regard, it advised Exxon during the public comment period as follows: "Two studies exposed rats to DIDP in feed, which the rats ingested, and two studies exposed rats to DIDP dissolved in oil (specifically olive oil in one case) and administered by oral gavage. The highest exposure reported in the NTP-CERHR monograph is 1.582 mg/kg-day, estimated from the rats' consumption of food containing 0.8 percent (or 8,000 parts per million) DIDP. DIDP was added to the diet in studies that treated rats with DIDP in feed. A corresponding exposure scenario in humans is ingestion of food contaminated with DIDP. Like other phthalates, DIDP is a hydrophobic, or highly lipophilic, organic compound. Therefore, administration of DIDP by oral gavage requires dissolving DIDP in organic solvents like olive oil. Levels of phthalates are much higher in fat-rich foods, such as milk or milk products, than that in foods containing low levels of fats. You stated in your letter that the 'maximum theoretical amount' of DIDP that could enter the human body from diet is 5.9 µg/kg-day . . . . If olive oil (or other oils or fats contained in foods) consumed by humans contained the level of DIDP used in the rat food study, a daily exposure of 5.9 µg/kg-day would be achieved by consumption of 42.8 mg/day of the oil

(approximately 0.0015 ounces). Human daily consumption of oil and fat-rich foods is apparently much higher than this amount. While the basis for the 'maximum theoretical amount' is not explained in your letter, it is clear that a significantly higher level of exposure could in fact occur via diet. Thus, whatever the *probability* that humans are actually exposed through ingestion to levels high enough to cause developmental toxicity, or even to require warnings about such exposures, these data establish unequivocally that such exposures are *possible*."

OEHHA makes a similar contention on appeal. While it does not contest Exxon's assertions concerning DIDP's low vapor pressure and low water solubility, it notes that DIDP is highly soluble in fats. Indeed, it notes, the studies cited by NTP relied on DIDP's fat solubility in their experimental design. Further, OEHHA contends that the studies cited by NTP prove that food can be contaminated with high levels of DIDP; that animals can ingest contaminated food; and that oral ingestion of DIDP can cause harm to the developing fetus. It concludes: "If rats can ingest food contaminated with high levels of DIDP, humans can do the same." This conclusion is not "'arbitrary, capricious, or entirely lacking in evidentiary support'" (*American Board of Cosmetic Surgery v. Medical Board of California*, *supra*, 162 Cal.App.4th at pp. 547-548), and thus we do not disturb it on appeal.

Second, OEHHA urges that Exxon's contention that DIDP cannot enter the human body in biologically significant amounts is not relevant to the issue now before the court, i.e., whether DIDP will be listed under Proposition 65. OEHHA contends that Proposition 65 creates a two-step procedure. "In the first step, Proposition 65 requires the Governor to publish a list of chemicals 'known to the state to cause cancer or reproductive toxicity.' (HSC § 25249.8, subd. (a).) . . . If a chemical is not on the list, Proposition 65 simply does not apply." "The second step of Proposition 65 occurs either twelve or twenty months *after* the chemical has been listed, when two separate requirements go into effect. The first prohibits businesses from discharging the listed chemicals into 'any source of drinking water . . . .' (HSC § 25249.5.) The second requires businesses to give clear and reasonable warnings before they expose individuals

to listed chemicals[.] . . . (HSC § 25249.6 . . . .) . . . The statute, however, permits a business to prove that it is exempt from both requirements. For reproductive/developmental toxicants, a business is exempt if it can prove that the specific exposure or discharge it causes will 'have no observable effect assuming exposure at one thousand (1000) times the level in question. . . .' (HSC §§ 25249.10, subd. (c); 25249.9, subd. (b), 25249.11, subd. (c).) . . . Further, businesses can request that the agency set . . . a 'safe harbor' level for a specific chemical, if none exists."

Based on this two-step structure of the statute, OEHHA contends as follows: "Exxon will have every opportunity to present its exposure argument, if and when it seeks to prove that it is exempt from the Proposition 65 requirements because a specific exposure that it causes is below the warning threshold. [Citation.] In fact, Exxon could present its exposure argument to OEHHA in seeking a Safe Use Determination under section [25404] of the regulations, or it could present its argument to the court in the future if it ever is sued for failing to provide a Proposition 65 warning. At such time Exxon will be entitled to prove, pursuant to the statute and the regulations, that the exposure it causes is 1000 times below the level that will have no observable effect. *Exxon's exposure argument is not, however, relevant to determining whether DIDP should be listed, and should not be addressed here.*" (Italics added.)

OEHHA's interpretation is consistent with the statutory requirements and, as we have said, OEHHA's interpretation of its own regulations is entitled to substantial deference. We thus do not disturb its interpretation on appeal.

DISPOSITION

The order denying appellant Exxon-Mobil Corporation's petition for writ of mandate is affirmed. Respondents shall recover their costs on appeal.

CERTIFIED FOR PUBLICATION

SUZUKAWA, J.

We concur:

EPSTEIN, P. J.

WILLHITE, J.